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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,190	12/04/2001	Jennifer L. Hillman	PF-0256-3 CON	2435

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INCYTE CORPORATION
3160 PORTER DRIVE
PALO ALTO, CA 94304

EXAMINER	
MONSHIPOURI, MARYAM	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,190	HILLMAN ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9,10,17-20 and 56-69* is/are pending in the application.

4a) Of the above claim(s) *9,10,19,20 and 62-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 17-18, 56-61, 69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 2-8, 11-16, 19 and 21-55 are canceled. been canceled. Claims 1, 17-18, 56-61 and newly presented claim 69 are still at issue and are present for examination. Claims 9-10, 20, 62-68 are withdrawn.

Applicants' arguments filed on 8/7/2003, paper No. 7, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 17-18, 56-61 and 69 remain rejected under the judicially created doctrine of double patenting over claims 1-2 of U. S. Patent No. 6,001,624 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as indicated in the previous office action.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

In response to this rejection applicant requested the terminal disclaimer requirement with respect to the '624 patent to be held in abeyance until the indication of allowable subject matter. Hence, the rejection remains for the reasons of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 17, 58, 61, and 69 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new matter rejection directed to claim 1 and claim 69 is withdrawn in view of applicant's amendment of the claims. However, In instant claim 1 part (c) and claim 69 applicant is claiming a

genus of SEQ ID NO:1 fragments which have not been adequately described structurally, in the specification, which renders said claim subject to written description rejection as following:

The specification does not contain any disclosure of the structure of claimed fragments beyond residues R6-V23 of SEQ ID NO:1. For example, what is the minimum length and composition of a polypeptide fragment comprising residues R6-V23 such that it is capable of retaining the appropriate conformation to bind mononucleotides? What critical residues in claimed fragments must always be retained to allow the right folding of the fragments for binding mononucleotides? etc. The genus of polypeptide fragments that comprise these above fragments is a large variable genus with the potentiality of encoding many different proteins that are not capable of binding mononucleotides. Therefore, many functionally unrelated fragments are encompassed within the scope of these claims. The specification discloses only a **single species** of the claimed genus (namely SEQ ID NO:1) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Since claimed fragments are not adequately described compositions comprising said fragments (claim 17, 61) are not adequately described either.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

In traversal of claim 58 new matter rejection applicant argues the following:

(1) that the specification explicitly discloses fragments of SEQ ID NO:1 comprising amino acid residues R6-V23. In addition, the specification discloses that the consensus sequence GXXGXGK is found at amino acid residues G14-K20. Since consensus sequence spanning residues G14-K20 is encompassed within the portion of SEQ ID NO:1 comprising residues R6-V23 and since the consensus sequence is "important for mononucleotide binding in AK", one of skill in the art would understand that residues R6-V23 of SEQ ID NO:1 play a role in the adenylate kinase activity of SEQ ID NO:1 (HMAK). Thus, according to applicant the specification provides an example of "fragments of SEQ ID NO:1 having adenylate kinase activity' by reciting the portion of SEQ ID NO:1 comprising residues R6-V23.

(2) The instant application claims priority to U.S. Patent application 08/829,027 (hereinafter "the '027 application). As filed, claim 1 of the '027 application reads as follows:

1. A substantially purified mitochondrial adenylate kinase comprising SEQ ID NO:1 or fragments thereof.

Therefore, in view of applicant , based on original claim 1 of the '027 application, fragments of SEQ ID NO:1 having adenylate kinase activity are not new matter.

These arguments were fully considered but were found **unpersuasive.** For the following reasons: **first**, the examiner is not clear as how binding to mononucleotides can be interpreted as adenylate kinase activity. Applicant is well ware that binding and

catalytic activity are two completely independent and distinct processes. This issue is further supported by the fact that in methods of assaying mononucleotide binding in the instant specification, applicant is using radioactive isotopes for monitoring the binding reaction and not kinase activity. Thus, the examiner respectfully disagrees with the applicant that specification provides an example of fragments having kinase activity by recitation of the portion of SEQ ID NO:1 comprising residues R6-V23.

With respect to applicant's **second** argument , the examiner again respectfully disagrees that original claim 1 in the '027 application is claiming a fragment with adenylate kinase activity. In contrast to applicant's view the examiner is of the opinion that no function is associated with said fragments in claim 1 of the '027 application. Applicant is also reminded that the '027 patent was issued before the implementation of new USPTO written description requirements, mentioned in the website above. Based on the new written description requirements the fragments such as those in claim 1 of the '027 patent are no longer allowable.

Therefore, in view of the arguments provided above, the new matter rejection directed to claim 58 remains for the reasons of record.

Finally, for the sake of argument, even if one assumes that said fragments of claim 1 of the '027 patent are recited as having kinase activity, claims 58, 61 and 69 remain rejected for reciting a **genus** of SEQ ID NO:1 fragments comprising residues R6-V23 of SEQ ID NO:1, which lack adequate written description requirement in terms of structure.

Applicant is well aware that for a polypeptide fragment to have kinase activity it must comprise at least 250-300 amino acids corresponding to the length of the catalytic site of kinases. The claimed genus of fragments merely comprising 17 amino acids of SEQ ID NO:1 are totally incapable of having kinase activity. Thus, some additional structural information about fragments that have kinase activity is required which is currently lacking in the specification.

Applicant in support of the claimed genus merely provided a single species, namely SEQ ID NO:1, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Since claimed fragments (claims 58 and 69) are not adequately described compositions comprising said fragments (claim 61) are not adequately described either.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 58 remains rejected under 35 U.S.C. 102(b) as being anticipated by Isogai (cited previously). Applicant's arguments in traversal of the new matter rejection, which are relied upon in overcoming this rejection, have already been addressed above.

Thus, the rejection remains for the reasons explained above in additions to those of record.

Allowable Subject Matter

An isolated polypeptide having at least 95% identity to SEQ ID NO:1, wherein said polypeptide retains adenylate kinase activity is free of prior art. Further the prior art does not teach or suggest such specifically claimed polypeptide. Hence, said polypeptide is also non-obvious.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571)

272-0932. The examiner can normally be reached on 7:00 a.m to 5:30 p.m. except for Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnanthapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

M. Monshi

Maryam Monshipouri Ph.D.

Primary Examiner

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